# EXHIBIT

# “I”

**IN THE UNITED STATES DISTRICT COURT**
**FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA**
**CHARLESTON DIVISION**

**IN RE: SYSTEM PRODUCTS LIABILITY LITIGATION**

**THIS DOCUMENT RELATES TO:**
Virginia ***Dubois v. Ethicon, Inc., et al.***

**HON. JOSEPH R. GOODWIN**

# RULE 26 EXPERT REPORT OF DR. WILLIAM PORTER, M.D.

## A. Qualifications and Background.

My name is William Edward Porter, M.D. I received a bachelor's degree in biology at the University of Michigan located in Ann Arbor, MI. I then went on and obtained a medical degree from the Wayne State University located in Detroit, MI. I subsequently completed a residency in obstetrics and gynecology at the University of Cincinnati and an American Board of Obstetrics and Gynecology certified three-year fellowship in Female Pelvic Medicine and Reconstructive Surgery (FPMRS) at the University of Tennessee Medical Center located in Memphis, Tennessee. I am one of the first ABOG Certified Physicians in the United States in the Field of (FPMRS). I served as a reviewer for the International Urogynecology Journal (2003 to 2006). I am currently a journal reviewer for Female Pelvic Medicine & Reconstructive Surgery. I serve on the American Urogynecology Society Coding Committee (2012 to 2016). I have lectured locally, nationally, and internationally on many subjects in the field of urogynecology and reconstructive pelvic surgery, including pelvic organ prolapse and urinary incontinence. I have taught at many medical device industry sponsored labs, the purpose of which has been to instruct other surgeons on the proper use of surgical devices and tools to treat pelvic organ prolapse and stress incontinence. I have also worked as a consultant to many medical device companies in developing and validating new products in the pelvic floor space.

I am trained extensively and practice exclusively in the field of pelvic medicine. This field encompasses pelvic organ prolapse, urinary incontinence, fecal incontinence, pelvic pain and pelvic floor dysfunction. Over the past 14 years post residency, I have performed nearly

3,000 pubovaginal slings (synthetic and xenographic) and fascia latta bladder neck slings. I have performed several thousand vaginal repairs for pelvic organ prolapse using native tissue, allograph, xenograph or synthetic augmented repairs. In the same regard I have also removed slings and mesh complicated surgeries (erosion and/ extrusion).

I have been specifically trained to use pelvic organ products (slings, graphs and mesh kits) by the following companies: C. R. Bard, Boston Scientific, Mentor, Cook Medical, Gynecare, American Medical System and Coloplast. I did complete any training required by said companies. I have been a trained proctor for the following companies: C.R. Bard, Boston Scientific, Mentor, Cook Medical, Gynecare and Coloplast. I have specifically treated female patients with the TVT mid-urethral sling.

Based upon my work as a urogynecologist (FPMRS), I am familiar with the medical complications that are generally associated with mesh repair surgery, and I am experienced in the recognition, diagnosis and treatment of patients suffering from complications caused by pelvic repair mesh implants and mid-urethral slings. The focus of my evaluation is the role that the TVT mid-urethral sling played in causing injury Dubois. The most common mesh-related complications are pelvic pain, scarring in the vagina and pelvic floor, pain into the legs and thighs, dyspareunia, chronic inflammation of tissue, chronic vaginal discharge or bleeding, scar bands or scar plates in the vagina, vaginal shortening or stenosis, erosion of mesh into tissues or organs, and nerve entrapment. In diagnosing and treating patients with mesh related complications, I often determine the likely cause of the patient's complications based upon a differential diagnosis, which typically includes a physical and history and a review of her medical records and other information about the patient.

In formulating the opinions set forth in this report I have relied on my personal knowledge, education and training, prior experience in treating stress urinary incontinence, medical literature, and a review of relevant medical records pertaining to Ms. Dubois. All of my opinions are true and correct to the best of my knowledge. I do reserve the right to supplement this report and my opinions if additional information becomes available (reports, discovery, articles or other relevant information). I also reserve the right to perform a physical examination on Ms. Dubois

**B. Summary of Materials Reviewed.**

I have reviewed the following medical records and depositions with accompanying exhibits pertaining to

Chenanago Memorial Hospital

Cleveland Clinic

North Medical

Cincinnatus Office

The Woman's Place

St. Joseph's Hospital Health Center

Deposition

## Summary of Medical Facts related to

**Virginia Dubois**

DOB 6/15/1961

**Past Medical History**

Anxiety, Hemorrhoids, MRSA

**Social**

Smoking

**Surgical History**

Appendectomy

Medications

Amlodipine, Prozac

9/19/2006

She had an endometrial ablation.

2/8/2011

She had a pelvic ultrasound that 12 x 7.4 x 4.8 cm uterus with uterine fibroids.

4/14/2011

She underwent a vaginal hysterectomy with bilateral salpingoophorectomy, anterior and posterior repair, paravaginal repair, vaginal vault suspension via uterosacral ligament, perineorrhaphy as well as a TVT-O sling with cystoscopy.

7/13/2012

Urodynamics: She voided 1023 ml with a peak flow 57 ml/s. She had a PVR 500ml.

11/23/2012

She has poor bladder emptying with poor void dribbling. She was started on Vagifem.

2/28/2013

She has a nabothian cyst. She reports difficulty with urinating. She reports her bladder has fallen again and she can see her bladder. She reports a high residual, 500 ml. She reports that she had a recalled mesh product. She reports her surgery worked for 6 months. She wants a referral to Cleveland clinic.

7/18/2013

Dr Paraiso did a Robotic assisted laparoscopic sacrocolpopexy, lysis of adhesions and umbilical hernia repair. She had presented to the Cleveland Clinic with complaints of bright red vaginal and rectal bleeding. She had significant voiding dysfunction including bladder spasm and incomplete voiding.

4/25/2017

She reports that she does not feel right. She reports that she had to return to Cleveland Clinic to repair an ineffective Mesh and has a law suit started. She remains on stool softeners.

Deposition

She reports something in her vagina.

**C. Methodology and Analysis.**

In determining the cause of a specific injury, it is customary to "rule in" potential causes of the injury, and then by process of elimination, to "rule out" the least likely causes to arrive at the most likely cause. This process is known as differential diagnosis, or differential etiology, and it is a well-established and universally accepted methodology for determining the cause of injuries employed by physicians throughout the United States. I often determine the cause of a patient's complications based upon an interview with the patient, a review of her medical records or knowledge of her prior medical history. I have used that methodology in arriving at my opinions in the case.

[1]As the vagina is a cleaned contaminated area, there is no way to completely eliminate bacteria from the surgical site. Implantation though this dirty field could allow bacteria to attach. These bacteria then can attach to the mesh and secrete a biofilm or a polysaccharide slime excreted by the bacteria. This slime could prevent the host defensive mechanism from clearing the infection. (Edmiston). This tissue response can contribute to the cause of vaginal pain, pelvic pain and chronic inflammation. This chronic inflammation/infection could be a source of pain. This chronic inflammation/infection could be a source of an erosion, vaginal discharge and possible UTI's. Dr. Daniel Elliott in his general expert report suggested the mesh creates a foreign body reaction and a chronic inflammatory response that can lead to chronic pain in the patient. The body's foreign body response to the mesh can cause a severe and chronic inflammatory reaction leading to excessive scarring in and around the mesh. The general expert witness group suggests that mesh degrades over time and causes a chronic foreign body reaction, fibrotic bridging, mesh contracture/shrinkage, fraying, particle loss, roping and

curling of the mesh contributing to pain. Daniel Burkley, a Principal Scientist has testified that polypropylene mesh in human beings is subject to some degree of surface degradation

The next step in my analysis was to rule out other potential causes. I did consider other potential causes including post-op scarring, perineorrhaphy, vaginal atrophy and granulation tissue from her hysterectomy. I also considered other factors in her history including her previous pelvic surgery and abdominal surgery. I considered each of these other risks for her pain and I concluded that they could not be ruled out as a source of her vaginal pain suffered by Virginia Dubois, but they could be ruled out as a source of her voiding dysfunction.

Additionally, it is my opinion to a reasonable degree of medical and scientific certainty, based on my background, education, training and experience, that Virginia Dubois treating physicians who implanted met the standard of care during implantation of the device. I found no evidence of surgical error or deviation from the requisite procedural steps. Further, after reviewing the operative reports, I see no evidence of any surgical complications.

**D. Conclusion.**

Based on the foregoing analysis, and based on my education, training and knowledge, it is my opinion to a reasonable degree of medical probability that the cause of Ms. Dubois' s voiding dysfunction is related to her TVT Mesh Implant. This pain is related to what the general experts described as a chronic inflammation around the mesh.

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I have the right to supplement and amend this opinion should additional factual information be forwarded to me that I did not have available at the time this opinion is submitted.

Dated this the 22th day of May 2017

William Porter, M.D.